User's Manual

RES-Q-VAC
Manual suction pump

CE 0123

This appliance conforms with the Directive 93/42/CEE "Medical Devices"

Guarantee of Quality system for the production and the final control of the products certified by the notifying body TÜV SÜD Product Service GMBH

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Thank you for choosing a Spencer product

1 GENERAL INFORMATION

1.1 AIM AND CONTENTS

The aim of this manual is to supply all the information necessary so that the client, will not only attain adequate use of the appliance, he will also be capable of using the instrument in the most autonomous and secure way possible. This includes information regarding technical aspects, functioning, maintenance, spare parts and safety.

1.2 CONSERVATION OF THE INSTRUCTION MANUAL

The instruction and maintenance manual must be kept with the product, inside the specially provided container and above all, away from any substances or liquids which could compromise perfect legibility.

1.3 SYMBOLS USED

SYMBOL	MEANING
	General or specific warning
	See instructions for use
/ SN	Lot number / Serial number
	Product code
	The product is compliant with the specifications of the Directive 93/42/CEE

1.4 SERVICING REQUESTS

For any information regarding the use, maintenance and installation, please contact the Spencer Customer Care Service on 0039 0521 541111 - fax 0039 0521 541222 - e-mail: info@spencer.it or write to Spencer Italia S.r.l. - Strada Cavi, 7 - 43044 Collecchio (Parma) - ITALY.

1.5 DEMOLITION

Follow the current regulations.

1.6 LABELLING

The serial number as indicated below can be found on each appliance and must not be removed or covered. In order to facilitate assistance please indicate or communicate the lot number (LOT) or serial number (SN) on the label.

2 WARNINGS

2.1 GENERAL WARNINGS

- Before carrying out any kind of operation on the appliance, the operator must carefully read the enclosed instructions, paying particular attention to the correct safety precautions and to the procedures to be followed for installation and for correct use.
- In the case of any doubts as to the correct interpretation of the instructions, please contact Spencer Italia S.r.l., for any necessary clarifications.
- Regularly check the appliance. Carry out the prescribed maintenance in order to keep the appliance in good condition and to guarantee correct functioning and a long life.
- In the case of any abnormalities or damage to the appliance, which could jeopardize the functioning and the safety, the appliance must be immediately removed from service.
- Do not alter or modify in any way the appliance; any such interference could cause malfunctions and injury to the patient and/or rescuer.
- The appliance must not in any way be tampered with. In such cases all responsibility will be denied for any malfunctions or injuries caused by the appliance itself. Those who modify or have modified, prepare or have prepared medical appliances in such a way that they no longer serve the purpose for which they were intended, or no longer supply the intended service, must satisfy the valid conditions for the introduction onto the market.
- Ensure that all the necessary precautions are taken in order to avoid the hazards that can arise as the result of contact with blood or body fluids.
- Handle with care.

2.2 SPECIFIC WARNINGS

- The device is only for use by trained staff.
- Do not abandon the device exposed to atmospheric agents.
- Do not use to suck inflammable substances.
- Suction should be carried out following the specifications given by your authorised local Medical/Health authorities.
- Some accessories could not be conform to the tubes supplied. It essential to check the compatibility of each accessory before use.
- Use of the device may require special precautions to be taken to avoid the risks of contagious diseases both during use, cleaning and connection of the tubes and jar.
- After having dismantled and re assembled the device, the user must carry out the test procedures indicated in paragraph 4.3.
- If during rescue operations the device should present any dysfunction, it must be substituted with a similar type of device so that the suction procedure is not interrupted.
- A spare jar must always be available so as to guarantee the continuity of suction.
- During use of the device, the patient must always have a trained operator at his side.

2.3 CONTRAINDICATIONS AND SIDE EFFECTS

The use of this device, if used as described in this manual, does not present any contra-indications or collateral effects.

3 DESCRIPTION OF PRODUCT

3.1 INTENDED USE

RES-Q-VAC is a suction device designed to collect non inflammable substances of only medical origin. RES-Q-VAC is an easy to use portable suction device particularly indicated for emergency situations; it does not require any power supply and it can be operated using the hands, knees or feet. It is used to free the patient's airways rapidly, safely and reliably.

All of its components are easy to remove and wash: RES-Q-VAC can be completely autoclaved. The accurate connections and the robust structure guarantee a long life span. The intervention on the device on behalf of the patient is not to be considered.

3.2 MAIN COMPONENTS

The principal components of the device are:

1. Shell
2. Pedal
3. Collection jar
4. Short tube
5. Long tube
6. Filter

SHELL: encloses the whole device; manufactured in polycarbonate.

PEDAL: permits the correct functioning of the device; it can be used either by pressure of the hand, foot or knee. Manufactured in stainless steel sheets coated with epoxy powder paint.

COLLECTION JAR: permits suction and collection of substances: manufactured in polycarbonate. Jar vase and the suction device and between the jar and the suction tube (not supplied with the device).

OVERFLOW VALVE: this valve will automatically close when the jar is full of suction liquid so as to avoid the liquids entering the internal parts of the pumps; it is manufactured plastic material.

FILTER: avoids any type of bacterial or viral contamination for the rescuer during use. It must be substituted after each use of the device. Manufactured in polytetrafluoroethylene (PTFE).

3.3 TECHNICAL DATA

DIMENSIONS	
Width	170 mm
Length	225 mm
Height	120 mm
Weight	1,3 kg
Maximum vacuum	-300 mmHg / -400 mbar
Average flow	22 L/min
Volume of collection jar	380 ml

3.4 ENVIRONMENTAL CONDITIONS

During use:

Temperature	from 0 to +40 °C
Atmospheric pressure	from 530 to 1100 hPa
Humidity	from 5 to 95%

During storage:

Temperature	from -40 to +70 °C
Atmospheric pressure	from 530 to 1100 hPa
Humidity	from 5 to 95%

4 OPERATING INSTRUCTIONS

4.1 TRANSPORT AND STORAGE

Before transporting the appliance, make sure that it is correctly packed ensuring also that there are no risks of shocks, bumps or falls during the transport itself.

Keep the original packaging for use in case of any further transport. Damage to the appliance caused during transport and handling is not covered by the guarantee. Repairs or replacement of the damaged parts are the responsibility of the client. If the device is not to be used for a long period, in addition to the advice already given, precautions must be taken regarding where the device is stocked and for how long:

- Stock in a closed area.
- Make sure the device is not subject to bump or vibrations.
- Protect the device from humidity and maintain a stable temperature.
- Make sure the device does not come into contact with corrosive substances.

4.2 PREPARATION

On receipt of the device check that all parts are present.

The device must be checked before each use so that any damage that may have been caused during storage or transport is detected.

1. Place the device on a flat surface (ex. shelf, trolley, table).
2. Insert the short tube on the suction outlet and into the lid on the vase in correspondence with the red float.
   The side of the protection filter with "IN" indicated on it must be attached towards the connection of the suction vase.
   Connecting the tube the wrong way could cause un repairable damage to the device.
3. Insert the long tube on the connector on the lid of the vase.
4. Action the pedal and close the end of the tube with your thumb to check that the device is sucking correctly.
   The device can be checked if the suction tube is immersed in a container of water.
   Check that the overflow valve is closed. If the overflow valve does not shut off correctly, it could cause damage to the device.

4.3 FUNCTIONING

After completing the essential preparation routine, the device is ready for use.

Start suction by continually pressing and releasing of the pedal until suction is completed. The pedal can be pushed using the foot, hand or knee.

The suction capacity is adjusted by the frequency of compression of the pedal.

Be careful to monitor that the overflow valve remains closed.

Keep a spare collection jar at hand ready for substitution if the vase in use is full.

When use terminates

When use of the device has terminated, the tubes must be disconnected (long and short ones) and the device must be accurately cleaned (paragraph 6) before placing the device back in the correct storage condition.

4.4 TROUBLESHOOTING

PROBLEM	CAUSE	REMEDY
The float has not closed	The float could have come un attached during the process of washing of the lid	Fit the float back in place

No suction occurs	Mucus overflows - Filter blocked up	1. Substitute the filter. 2. Check the O ring is present and that it is in good condition.
	Tube connection is not correct	Connect the long and the short tube correctly
	Obstruction of tubes	Clean or substitute the tubes
	Tubes cut	Substitute tubes
	Incorrect position of long tube (crinkling)	Check that the position of the tubes does not cause crinks
	The collection jar does not create vacuum	1. Check and/or screw on the lid. If the problem is not resolved contact the assistance centre. 2. Check the O-ring on the lid is present and that it is in good condition.
	When using the pedal, not vacuum is created	Contact the assistance centre

5 MAINTENANCE AND CLEANING

5.1 CLEANING

Failure to carry out the correct cleaning operation is a risk for cross infection. In order to maintain the device correctly, the following cleaning procedure must be periodically carried out:

Cleaning the collection jar

Keep the collection jar on its support and remove the lid. The vase can then be removed from the support and emptied.

The collection vase must be accurately cleaned after each use, as follows:

a. Clean rubbing with alcohol and leave to dry.
b. Wash with hot water and washing up liquid a rinse under hot running water. Proceed washing with hot water and white vinegar (one part white vinegar/three parts water). Rinse with running hot water and leave to dry.
c. Wash with any disinfectant available on the market (bacterial and germicide), carefully following the instructions given with the product.

Cleaning the shell

Clean the shell with a clean cloth and disinfectant available on the market (bacterial and germicide), carefully following the instructions given with the product.

Cleaning the tubes

1. Remove the tubes from the device.
2. The tubes must be rinsed after each use using hot water from the tap and then rinsing with a solution of hot water and vinegar (one part white vinegar/three parts water).
3. Rinse with hot water and leave to dry.
4. Clean the outer surface of the tubes using a clean cloth.

5.2 MAINTENANCE

5.2.1 Precautionary maintenance

The person who carries out the precautionary maintenance of the appliance (user in person, manufacturer/supplier or a third party) has to guarantee the following basic requirements:

- Technical knowledge of the appliance and of the periodic maintenance procedures as described in these instructions.
- Specific qualifications and training in the maintenance operations of the appliance in question.
- The use of components/replacement parts/accessories that are either original or approved by the supplier, in such a way that each operation causes no alteration or modification to the appliance.
- Possession of the checklist of operations carried out on the appliance.
- Guarantee complete adherence to the instructions of the Directive 93/42/CEE which includes also the obligation towards the manufacturer to maintain post sales records and traceability of the appliance if requested.

The device must undergo complete servicing every year by the manufacturer or by an authorized service centre.

The person responsible for every day maintenance can only substitute the spare parts indicated on paragraph 6.2 "Spare Parts".

All other substitutions or repairs can be carried out only by the manufacturer or by a centre authorised by the manufacturer.

5.2.2 Special servicing

Only the manufacturer or centres with written authorisation are authorised to complete any special servicing operations.

The device, if used as indicated in the following instruction manual, has an average life span of 5 years. The life span can be expanded only following a general revision of the product that must be carried out by the manufacturer or by a centre authorised by the manufacturer.

6 ACCESSORIES AND SPARE PARTS

6.1 ACCESSORIES

DG00150A	YANKAUER SUCTION TUBE
DG00212C DG00214C DG00216C DG00218C	SUCTION CATHETERS
RV71104A	RVX 04 TRANSPORT BAG RES Q VAC IN ORANGE PVC

6.2 SPARE PARTS

RV71106C	ANTIBATERICAL FILTER
RV71102A	SPARE COLLECTION JAR AUTOCLAVABLE WITH OVERFLOW VALVE 0,380 L
RV71107A	SPARE LID FOR RES-Q-VAC JAR
RV71105A	MEMBRANE BOARD FOR RES-Q-VAC
OX10103A	SILICONE SUCTION TUBE FOR SUCTION DEVICE Ø 5x9 mm (PER METER)
SC70088A	DOUBLE SUCTION CONE

Warning

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